DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 17, 2015

Heka Dental A/S
c/o Mr. Dave Yungvirt
Third Party Review Group, LLC
45 Rockefeller Plaza, Suite 2000
New York, NY 10111

Re: K150490
Trade/Device Name: UnicLine Mobile
Regulation Number: 21 CFR 872.6640
Regulation Name: Dental Operative Unit and Accessories
Regulatory Class: I
Product Code: EIA
Dated: April 3, 2015
Received: April 6, 2015

Dear Mr. Yungvirt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Not Yet Known. K150490

Device Name
UnicLine Mobile

Indications for Use *(Describe)*
The UNICLINE MOBILE is an electrically powered, self-contained mobile dental operative unit intended to supply power to and serve as a base for other dental devices and instruments. The system is indicated for performing general dental procedures. The device is intended for operation and use in a clinical setting by legally qualified professionals.

Type of Use *(Select one or both, as applicable)*

[X] Prescription Use (Part 21 CFR 801 Subpart D) [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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SECTION 5: 510(k) SUMMARY
AS REQUIRED BY 21 CFR 807.92

510(k) Summary

Date Prepared:	February 12, 2015
Submitter:	HEKA DENTAL A/S Baldershøj 38 DK-2635 Ishøj Denmark. Telephone: +45 43 32 09 90 Facsimile: +45 43 32 09 80
Contact:	Cynthia J. Pillar, RAC Phone: 1 (773) 677-8886
Trade/Proprietary Name of Device:	UNICLINE MOBILE
Common Name of Device:	Dental Operative Unit
Classification:	Class I per 21 CFR 872.6640, Operative Unit, Dental, Product Code EIA
Legally Marketed Predicate Device:	Aseptico AMC 20 Mobile Dental System, K101332) Class I per 21 CFR 872.6640, Operative Unit, Dental, Product Code EIA, manufactured by Aseptico, Inc.
Reference Device:	Planmeca Sovereign Dental Operative Unit, K081699 Class I per 21 CFR 872.6640, Operative Unit, Dental, Product Code EIA, manufactured by Planmeca USA, Inc.

Description of New UNICLINE MOBILE Device:

The new UNICLINE MOBILE is an electrically powered, self-contained mobile dental operative unit consisting of a mobile cart, foot control, internal water supply containers, suction, and mobile patient chair. It contains a foot control that allows the dental professional to engage the features using only the foot. Instrument status is viewable in a single place using a multi-display feature. The instrument arms are spring balanced for ease of use and the extra long connection hoses have been designed for use in any position. The new UNICLINE MOBILE is designed to ensure patient comfort and safety in any of

the chair positions. The handles, instrument support, and upholstery are easy to disassemble and clean.

The unit uses compressed air and water, and includes a suction element. The cart contains the motors that operate the instrument connections. There are two movable arms that protrude from the top of the cart. One arm contains the optional OEM dental operating lamp that the dentist can position to light the area being worked on. The other arm supports an instrument table. The table contains five spring-loaded smaller arms, an instrument tray, and the instrument display. The new UNICLINE MOBILE spring-loaded arms connect with OEM dental instruments and provide power to them. Once connected, the display indicates whether the air and water spray are on, the time, and the speed of the active motor. The display also includes a timer for use with a light polymerization instrument. The dental professional uses the foot control to operate all functions and instruments of this dental operative unit.

The unit was designed for mobility and ease of positioning. The cart is made of fire retardant medium density fiberboard (MDF) coated with paint and its two arms are made of anodized, lacquered aluminum. All selected materials are biocompatible. The chair is made with casted aluminum and imitation leather upholstery. Both the cart and chair contain wheels on one side to allow each piece to be positioned for optimal use of available floor space before connecting via the stabilizing plate.

Intended Use/Indications for Use of the New Device:

The UNICLINE MOBILE is an electrically powered, self-contained mobile dental operative unit intended to supply power to and serve as a base for other dental devices and instruments. The system is indicated for performing general dental procedures. The device is intended for operation and use in a clinical setting by legally qualified professionals.

The indications for use statements of the new UNICLINE MOBILE device and the predicate Aseptico AMC 20 Mobile Dental System device are nearly identical. The new UNICLINE MOBILE indications for use statement includes specific information concerning its use environment, use of instruments, and intended users. This information also applies to the predicate device, but they are not included in the indications for use statement. In addition, the new UNICLINE MOBILE is indicated for general procedures without additionally specifying endodontic procedures, as general procedures encompass general endodontic procedures. These differences are not critical to the intended use of the new UNICLINE MOBILE device, nor do they affect the performance of the device when used as labeled.

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Comparison of the Technological Features of the New Device and Predicate Device:

We believe that the new UNICLINE MOBILE device has been shown to be substantially equivalent to the predicate Aseptico AMC 20 Mobile Dental System (K101332). The new and predicate devices are very similar in overall design and technology, principles of operation, intended use, materials, construction, and compatibility with OEM instruments. Main differences are as follows:

1. The new UNICLINE MOBILE cart can be purchased with an optional OEM dental operating lamp and arm that connects to the cart. The predicate AMC 20 Mobile Dental System (K101332) does not offer this optional feature.

2. The new UNICLINE MOBILE cart contains an instrument arm and is mounted to a mobile patient dental chair designed specifically for the new UNICLINE MOBILE device. The predicate device contains instrument mounts directly on the side of the cart and does not mount to a dental chair. The two devices are similar since both are used with a dental chair and mounted instruments and both must be stable in order for safe and effective use.

The differences between the new UNICLINE MOBILE device and the predicate Aseptico AMC 20 Mobile Dental System device do not raise any new questions.. Shown in TABLE 5.1 below are some select properties and characteristics of the new UNICLINE MOBILE and the predicate Aseptico AMC 20 Mobile Dental System device compared side-by-side.

DESCRIPTIVE INFORMATION	NEW UNICLINE MOBILE DENTAL OPERATIVE UNIT	PREDICATE DEVICE: Aseptico AMC 20 Mobile Dental System (K101332)	Substantial Equivalence
Indications for Use	The UNICLINE MOBILE is an electrically powered, self-contained mobile dental operative unit intended to supply power to and serve as a base for other dental devices and instruments. The system is indicated	The AMC-20 is a mobile self-contained dental system that is used for endodontic and general dentistry applications.	Similar – No new question of safety and effectiveness

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	for performing general dental procedures. The device is intended for operation and use in a clinical setting by legally qualified professionals.		
Product Code	EIA	EIA	Same
Regulation Number	872.6640	872.6640	Same
Regulation Name	Unit, Operative, Dental	Unit, Operative, Dental	Same
Intended Users	Dentists, Assistants & Hygienists	Dentists, Assistants & Hygienists	Same
Environment of Use	Clinical Setting	Clinical Setting	Same
Protection Class	Class 1 equipment	Class I equipment	Same
Degree of Protection	Type B of applied parts Type BF Equipment	Type B of applied parts Type BF Equipment	Same
Power Supply	120V/230V 50/60Hz electrical supply	100V/220V at 60Hz/50Hz	Similar – no new question of safety or effectiveness.
Frequency	Mains Frequency: 50/60Hz	Mains Frequency: 50/60Hz	Same
Utility Supply	Compressed Air and Water	Compressed Air and Water	Same
Electrical Safety	IEC 60601-1	IEC 60601-1	Same
EMC	EN 60601-1-2	IEC 60601-1-2	Same
Display	LED	LED	Same
Materials	Fire retardant MDF, Aluminum	Stainless Steel, Aluminum, Plastic (Fire Retardant MDF – unknown)	Similar – no new question of safety or effectiveness
Dimensions (Installed)	Cart: 22.8” W x 26.2” L x 34.3” H	Cart: 23.5” W x 30.0” L x 36.5” H	Similar – no new question of safety or effectiveness
Weight	Cart 90Kg (198 lbs) (Chair 95Kg,	71.7Kg (158 lbs)/ (OEM Chair Unknown)	Similar – no new question

	Total 185Kg)		of safety or effectiveness
Features	2 motors for OEM instruments 3-way air/water syringe Self-contained water system Air supply Suction Foot Control Movable arms Dental Operating Lamp	2 motors for OEM instruments 3-way air/water syringe Self-contained water system Air supply Suction Foot Control	Difference – see explanation 1. above for lamp & 2. above for the movable instrument arm
Dental Chair	Cart mounts to Heka Dental chair	Cart does not mount to chair	Difference – see explanation 2. above
Air Pressure	65 - 88psi – default setting 110 psi - max	110psi	Same
Water Supply – Flow Rate	0.15 liter/min	5.07 fl. oz./min (0.15 liter/min)	Same
Suction Connection – Flow Rate	67.0 – 80.0 Liters/Min	42.3 – 189.7 liters/min	Similar – no new question of safety or effectiveness

TABLE 5.1

Testing:

Non-Clinical Performance Data Testing:

Performance bench testing was conducted to verify that the new UNICLINE MOBILE device meets all design specifications and demonstrates substantial equivalence to its predicate Aseptico AMC 20 Mobile Dental System (K101332). The results of testing demonstrate that the new UNICLINE MOBILE device complies with the following standards:

- IEC 60601-1 - Medical electrical equipment – part 1, General requirements for safety
- IEC 60601-1-2 - Medical electrical equipment - part 1-2, General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility, Requirements and tests

- IEC 60601-1-6 – Medical electrical equipment – Part 1-6: General Requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366 – Medical devices – Application of usability engineering to medical devices
- IEC 80601-2-60 - Medical electrical equipment – Part 2: Particular requirements for basic safety and essential performance of dental equipment
- ISO 7494-2 - Dentistry – Dental Units – Part 2: Water and air supply
- ISO 7494-1 - Dentistry – Dental Units – Part 1: General requirements and test methods
- ISO 21530 - Dentistry – Materials used for dental equipment surfaces – Determination of resistance to chemical disinfectants
- ISO 6875 – Dentistry – Patient Chair

Biocompatibility:

The new UNICLINE MOBILE direct and indirect patient contacting materials are biocompatible. The direct patient contacting upholstery is the same material and color as used in reference device, the Planmeca Sovereign Dental Operative Unit, K081699. The indirect patient contacting materials comply with 21 CFR 177.2600.

Software:

In addition, the software has been validated and complies with the FDA Guidance for the content of Premarket Submission for Software Contained in Medical Devices as well as IEC 62304: 2006, Medical device software – Software life cycle processes.

Risk Analysis:

Risk management activities were performed throughout development of the new UNICLINE MOBILE unit. Potential individual risks were identified, evaluated, and mitigated to the extent possible. Remaining overall residual risk was assessed and determined that any remaining risk is as low as possible and is outweighed by the benefits of the new UNICLINE MOBILE.

Clinical Performance Testing:

No clinical testing has been performed in support of this UNICLINE MOBILE 510(k) submission.

Conclusion:

The conclusions drawn from the specifications and performance testing of the new UNICLINE MOBILE device demonstrate that the new UNICLINE MOBILE device is at least as safe and as effective and performs as well as the predicate Aseptico AMC 20 Mobile Dental System (K101332). For these reasons, we believe the new UNICLINE MOBILE device is substantially equivalent to the predicate device.